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Joseph R Snyder			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Sunshine et al.

Application No. 09/600,346

lo. Applicant(s)

Office Action Summary Examiner

Karl Easthom

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 1) Responsive to communication(s) filed on Sep 27, 2001 2b) This action is non-final. 2a) This action is FINAL. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. **Disposition of Claims** _____ is/are pending in the application. 4) X Claim(s) 1-28 4a) Of the above, claim(s) 18-28 is/are withdrawn from consideration. 5) Claim(s) 6) Claim(s) 1-17 is/are rejected. 7) Claim(s) ______ is/are objected to. are subject to restriction and/or election requirement. 8) Claims **Application Papers** 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are objected to by the Examiner. 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) 💢 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) ☑ All b) ☐ Some* c) ☐ None of: 1. Certified copies of the priority documents have been received. 2. L Certified copies of the priority documents have been received in Application No. 3. X Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 15) X Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152) 20) Other: 17) X Information Disclosure Statement(s) (PTO-1449) Paper No(s). ___5

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1. Applicant's election with traverse of claims 1-17 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the reference noted does not disclose aligned conductors. This is not found persuasive because other references as noted below disclose same.

The requirement is still deemed proper and is therefore made FINAL.

- 2. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).
- 3. The attempt to incorporate subject matter into this application by reference to WO 99/00663 (page 17) is improper because it is a foreign reference and the material attempted to be incorporated appears to be essential. There is no disclosure of a claimed sensor array for detecting an analyte (assuming the preamble creates a claimed element) having the materials claimed in claims 8-16. Only carbon black is disclosed in Example 2. No other conductive materials are disclosed as capable of sensing. As noted below, all of the claimed structure is seen in Simendinger, and the other references noted. If only the sensors of WO 99/00663 can be employed for detecting an analyte, these must be disclosed.

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4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As noted above, there is no disclosure of a claimed sensor array for detecting an analyte (assuming the preamble creates a claimed element) having the materials claimed in claims 8-16. Only carbon black is disclosed in Example 2. No other conductive materials are disclosed as capable of sensing analyte.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The specific polymer that can absorb analyte is critical or essential to the practice of the invention, but since it is not included in the claim(s), it is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). That is, applicant at page 17, and Lewis et al. (WO 99/00663) disclose that the devices require polymers that can absorb fluid. Without such a polymer, a simple alignment of conductive regions, as claimed, sans that polymer or any polymer, could not absorb same and detect analyte.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Black Pearl aligned in poybutadiene, does not reasonably provide enablement for a simple alignment of conductive regions without a polymer. Nor is there

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enablement or written description for the class of conductive materials claimed in any of claims 817 for reasons noted above (carbon black only is disclosed). The specification does not enable
any person skilled in the art to which it pertains, or with which it is most nearly connected, to the
invention commensurate in scope with these claims.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
- 7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Murata et al. or Meiklejohn. In Murata, the sensors 4 are in an array and "aligned" where they are in a line and parallel to one another in any of the Figs. 1-4. Similarly the sensors 19 are aligned in the holes of the substrate, with alternate nonconducting regions in the substrate 11. In claim 3, mechanical processes produced the device.
- 8. Claims 1-7, 10-11, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Jin et
- al. Jin discloses the claimed sensor at Figs. 3 or 5, where the aligned material is 34 or 53.

 The structure can be used to detect an analyte since it is the same as the disclosed structure and claimed structure. Or, alternatively, the phrase "for detecting an analyte" is given no patentable weight as a statement of intended use. In claims 3-7, how the particles are aligned are

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process distinctions only that creates no resulting distinct product. The disclosed product of Jin is the same as the claimed product no matter how formed since the resulting product has aligned particles.

- 9. Claims 1-7, 9-10 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Keen. Keen discloses the claimed invention at Fig. 2 with aligned conductive material the conducting Circuitry (electrical measuring apparatus) is disclosed at col. 12, lines 38polymer strands 16. Also note that DNA can be employed as the conductive strands, with a width of 20A -55. It is also noted that elements 18, termed "head thus being aligned, see col. 13, lines 36-39. groups" at col. 13, detect analyte, and are "aligned" over the elements 16. See col. 7, lines 35-40 - "molecular recognition groups aligned in a common orientation". See also col. 23, lines 3-67, where the head groups 18 are aligned via an electric field, col. 23, lines 40+ and specifically lines 60-66, since they are "uniaxially oriented" via an electric field. In claims 4-6, the electric alignment also has a magnetic field, since all electric fields do. Same is induced by light at col. 23, lines 5-20. In claim 9, the electrons or charge transport is a nanoparticle. In claims 10 and 15, metal, iron oxide or silicon dioxide are disclosed at col. 25, lines 25-40. In claims 7 and 9, the molecules are composites that are nanoparticles given the size of strands 16 at col. 13, lines 32-37 in the nanometer range.
- 10. Claims 1-16 rejected under 35 U.S.C. 102(b) as being anticipated by Simendinger, III et al. Simendinger discloses all the conductive material of claims 8-15 at claim 12, and col. 4, lines 39-67, where col. 3 discloses that the conductive components of the first second polymers may be

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the same. The alignment is as depicted at Fig. 1 for the second polymer. Claims 3-6 are met regardless of the method employed for alignment as noted above. Further, magnetic alignment, disclosed at col. 5, cannot occur without an electric field. Particle sizes of 10 nanometers are disclosed as .01 microns at col. 5, line 11, and are deemed to be nanoparticles of claim 9. Any of the wide class of polymers disclosed at cols. 1-2 are capable of performing the analyte function, assuming it is a claimed element.

- 11. NOTE: As evidence that the polymers disclosed in Simendinger can be used to detect an analyte, see page 16 of Lewis WO '663 -(a wide class including polycarbonates, polyesters, etc are disclosed which are the same as the claims noted in col. 3 of Simendinger, III. This remark pertains to the other references where the class is so large, the organic polymers disclosed in the references applied are expected to also be capable of detecting an analyte. The 112 rejections noted above might be overcome by amending to incorporate the essential material and claiming the required polymers and/or conductive elements, assuming there is support in the documents incorporated by references. However, evidence must be supplied to counter the assertion of the inherent ability of the aligned devices to detect analyte to overcome the prior art rejections. This burden is shifted to applicant since the materials in Simendinger, III (at least) are the same as that in Lewis as noted.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Easthorn whose telephone number is (703) 308-3306.

KARL D. EASTHOM BRIMARY EXAMINER

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